

Development and Supply of Vaccines: An Industry Perspective

Michel Gréco

Independent Vaccine Expert, Formerly Aventis Pasteur, Lyon, France

Luc Hessel

Policy Affairs, Europe, Sanofi Pasteur MSD, Lyon, France

INTRODUCTION

The inception of the 21st century represents a period of great change in the geopolitical approach to vaccinology. Empiricism has given way to more scientific strategies using the most innovative technologies, and several new vaccines against diseases that were not previously preventable are now available. This leads us to reexamine some of the priorities that until now have driven the conception, proposition, and adoption of vaccination policies. The introduction of new vaccines has and will have a major impact on national budgets and the ways in which vaccination programs are funded. These changes in the socioeconomic environment of vaccination encourage undertaking a fundamental overhaul of prevention policies and their financing. However, this in turn will affect the structure and dynamics of the vaccine market and the challenges faced by the vaccine industry.

The future is bright for vaccinology, on the basis of a series of strengths and opportunities. However, there also exist weaknesses and threats, and they must be addressed. The major strength lies in the current and future major scientific advances relevant to vaccines. Indeed, vaccines currently represent the most innovative part of the pharmaceutical industry. Opportunities reside in improving the public's perception of the value of vaccines and the necessity for their development and implementation, triggered by concerns over existing infectious disease threats, emerging infectious diseases, bioterrorism, pandemic influenza, and other factors. From an industrial perspective, a weakness derives from the relatively minor contribution that vaccines make overall to the pharmaceutical market, where they are often viewed as overly expensive and as an expenditure rather than a cost-effective investment in public health. There is also the imbalance between the pressing needs of developing countries and considerations of cost-effectiveness in developed countries. As for uncertainties that concern the vaccine industry, they include shortfalls in funding for programmatic national vaccination policies and the negative safety perceptions held by segments of the general public in industrialized countries. Some other uncertainties relate to production capacity issues and research challenges.

THE WORLD VACCINE MARKET, PRESENT AND FUTURE

The notion that vaccines constitute a credible and reliable financial market is fairly recent. Apart from smallpox (Jenner), rabies (Pasteur), and inactivated whole-cell parenteral typhoid vaccine (Wright and Pfeiffer) (see chap. 1), almost all vaccines were discovered in the 20th century, mostly in the second half of the century. During the first years of the 21st century, six new vaccines have already been licensed, expanding the number of vaccine-preventable diseases from 22 to 25. Within the pharmaceutical industry, vaccines were historically set apart because of the close interactions between industry and public health authorities in relation to these products; for many years, they were basically viewed as not-for-profit or minimal-profit products (1). As a result, as recently as the late 1980s, most pharmaceutical companies were leaving the field of vaccines (2). A number of factors have combined to reverse the tide so that today vaccines are a much more competitive commercial area (3). Nevertheless, the field remains at best a "qualified" market that is strongly regulated and has high entry barriers and supply constraints, is largely "monopsonistic" in nature, and must adjust to specific price-setting mechanisms (4).

The vaccine "market" actually comprises three major subsets:

The so-called "closed markets" where local producers supply the local needs with mostly Expanded Program on Immunization (EPI) monovalent vaccines, which generally cannot be exported, mainly for regulatory reasons, and the value of which cannot be readily assessed (5,6). This segment is evolving with the emergence of new major economies such as China, Brazil, and India, and the development of strong local producers. In the medium term, one should expect increased competition from and in these markets.

"Donors' markets" managed by international organizations [WHO, UNICEF, Pan American Health Organization (PAHO), Global Alliance for Vaccines (GAVI, now called the GAVI Alliance), etc.] who buy mostly EPI